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In re Application of :
Bertram Cezanne et al :
Serial No.: 10/519,356 : PETITION DECISION
Filed: December 28, 2004 :
Attorney Docket No.: MERCK-2952 :

This is in response to the petition under 37 CFR 1.144, filed September 27, 2006, requesting withdrawal of an improper Lack of Unity requirement.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 371 and accepted on December 28, 2004, and contained claims 1-33. In a first Office action, mailed January 17, 2006, the examiner set forth a Lack of Unity between the inventions set forth in claims 1-33, as follows:

Group I – Claims 1-25 and 27-30, drawn to compounds of Formula I which is N[4-(2-thioxopyrrolidin-1-yl)phenyl]-2-(3-aminomethyl-phenyl)-5-trifluoromethyl-2H-pyrazole-3-carboxamide;

Group II – Claims 1-25 and 27-30, drawn to compounds of Formula I which is N[4-(2-iminopyrrolidin-1-yl)phenyl]-2-(3-aminocarbonyl-phenyl)-5-trifluoromethyl-2H-pyrazole-3-carboxamide;

Group III – Claims 1-25 and 27-30, drawn to compounds of Formula I which is N[3-chloro-4-(2-thioxopyrrolidin-1-yl)phenyl]-2-(3-aminocarbonyl-phenyl)-5-trifluoromethyl-2H-pyrazole-3-carboxamide;

Group IV – Claims 1-25 and 27-30, drawn to compounds of Formula I which is N[4-(2-iminopyrrolidin-1-yl)phenyl]-2-(3-aminocarbonyl-phenyl)-5-trifluoromethyl-2H-pyrazole-3-carboxamide;

Group V – Claims 1-25 and 27-30, drawn to compounds of Formula I which is N[4-(2-methoxyiminopyrrolidin-1-yl)phenyl]-2-(3-aminocarbonyl-phenyl)-5-trifluoromethyl-2H-pyrazole-3-carboxamide;

Group VI - Claims 1-25 and 27-30, drawn to compounds of Formula I which is N[3-methyl-4-(2-methoxyiminopyrrolidin-1-yl)phenyl]-2-(3-aminocarbonyl-phenyl)-5-trifluoromethyl-2H-pyrazole-3-carboxamide;

Group VII – Claim 26, drawn to a method of preparation of the compounds of Formula I;

Group VIII – Claims 31 and 33, drawn to the use of the compounds of Formula I

Group IX – Claims 32, drawn to kits containing compounds of Formula I.

The examiner indicated the above list was not exhaustive and allowed applicants to select another compound within the scope of Formula I for examination purposes. The examiner indicated the compounds lacked Unity due to the variety of substituents and the lack of a common core which made a contribution to the art.

Applicants replied on February 17, 2006, amending claims 1-33 and adding claims 34-44. Applicants elected the compounds of Group I with traverse. Applicants argued that all of the compounds of Groups I-VI should be examined together as they have a common property or activity and possess a common significant structural element.

The examiner mailed a new Office action to applicants on April 20, 2006, acknowledging the election of Group I and the traverse, but maintaining the requirement, and making it Final without substantively responding to applicants' arguments for traversal. The examiner then indicated that the examination would be limited to compounds of Formula I where D is absent, M is a phenyl ring, W is pyrazole bonded to the phenyl ring at the 1-position, R¹ is CH₂NH₂ bonded meta to the pyrazole ring and X is CONH, all other substituents being as defined. Claims 1-3 and 6-31 were objected to as containing non-elected subject matter. Claims 27-28 were rejected under 35 U.S.C. 112, first paragraph, as lacking enablement. All other examined claims were indicated as free of the prior art.

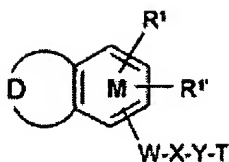
Applicants replied on July 20, 2006, adding claims 45-58 and traversing the Lack of Unity requirement again. Applicants also responded to the rejection of record.

The examiner mailed a Final Office action to applicants on September 15, 2006, discussing the Lack of Unity holding further and indicating the expansion of the compounds searched based on the compound elected. The objection to the claims as containing non-elected subject matter was maintained as was the rejection under 35 U.S.C. 112, first paragraph, as lacking enablement.

This petition was filed on September 27, 2006, traversing the Lack of Unity requirement. A response to the Office action was filed on November 3, 2006, but has not yet been considered by the examiner pending decision on this petition.

DISCUSSION

A review of the claims, as filed, shows that they are directed to compounds based on the following structure:



Each of the variables is defined (or in some cases may be absent). It is noted that each element of the above structure is a variable. For instance, D is defined as absent or 3-4 member alkylene chain with 1-3 members being replaced by N, O or S and may be substituted; M is a phenyl ring which may contain 1-2 N, O or S atoms; R^1 and $R^{1'}$ may be H, halogen, or various other substituents; W is a mono- or bi-cyclic saturated or aromatic carbocyclic or heterocyclic ring having 1-4 N, O or S atoms; X is CONR^2 or similar substituents; Y is alkylene, cycloalkylene, aromatic-diyl; or heteroaromatic-diyl; and T is a mono- or bi-cyclic saturated or aromatic carbocyclic or heterocyclic ring having 1-4 N, O or S atoms and other substituents on the ring. From the above it can be seen that there is no significant structural feature common to all compounds and therefore, Unity is lacking, *pro forma*. (See PCT Administrative Instructions, Chapter 10, Example 24.)

Claim 1, as noted, sets forth the definition of the various elements of Formula I and claims 2-24 set forth more limited definitions of one, or in some cases more than one, of the variables, but in no instance can a single significant structural element be determined which would form the basis for finding Unity among a group of compounds. Claim 25, however, sets forth 24 specific compounds, all but two of which are 5-trifluoromethyl-2H-pyrazole-3-carboxamides. The examiner set forth several representative examples from this claim as Lacking Unity and required election therebetween. Such was improper as this equated to an election of species requirement. Upon election, however, the examiner did set forth definitions of the variables as where D is absent, M is a phenyl ring, W is pyrazole bonded to the phenyl ring at the 1-position, R^1 is CH_2NH_2 bonded meta to the pyrazole ring and X is CONH which is in general accordance with the species set forth in Claim 25 and created a structure which constitutes a significant structural element. Based on this it appears the examiner has considered the 5-trifluoromethyl-2H-pyrazole-3-carboxamide as the base structure providing the required significant structural element for Unity. Thus Groups I-VI appear to have been, at least, informally considered together.

Applicants argue that the examiner has not considered section (f) of Annex B with respect to determining Lack of Unity. Annex B has now been incorporated into Chapter 10 of the Administrative PCT manual. No substantive changes were made due to this incorporation. Applicants argue that all compounds encompassed within the claims have a common property. No disagreement with this statement is made. However, applicants' argument that all compounds encompassed within Claim 1 possess a significant structural element is not valid. As the examiner has noted, Example 24 addresses claims containing Markush groups defined by a series of variables, as here, and indicated that there cannot be Unity as there is no common structure. In essence, claim 1 contains numerous significant structural elements which may have Unity with respect to a number of compounds encompassed within the claim, but not with each other. The only compounds initially set forth in the claims having a semblance of Unity are those set forth in Claim 25 which, as noted above, have been or are rejoined as possessing Unity.

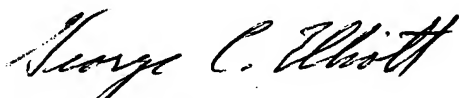
The examiner should determine whether any added claims also possess Unity with the compounds of Claim 25 and include them with the claims examined. Applicants should cancel subject matter from the claims which does not have Unity with the above determined significant structural element.

DECISION

The petition is **GRANTED-IN-PART** in that the 5-trifluoromethyl-2H-pyrazole-3-carboxamides of claim 25 are found to possess Unity and have been or will be examined fully.

The application will be forwarded to the examiner for consideration of applicants' reply filed November 3, 2006, and further action not inconsistent with this decision.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number, 571-273-8300.



George C. Elliott.
Director, Technology Center 1600